right to a common owner. The policy is applied so that a common owner of plural patent applications which allegedly claim embodiments which are no more than obvious variants of one another is not allowed to obtain patent rights beyond the expiration date of the first-allowed application.

However, the doctrine cannot apply if plural applications are not commonly owned because the rights belong to different owners. Therefore, the right to exclude for the different patents will be vested in different owners and thus, the patent rights would be in competition rather than held by a single entity.

There is no unjustified time-wise extension of patent right to a single owner as to the instant application because the relied on patent and the instant application are owned by different entities.

As stated throughout the record and repeated herein by reference in entirety, it is believed the obviousness-type double patenting rejection is improper and must be removed.

In item 20 bridging pages 4 through 6 of the Office Action, the claims remain rejected under 35 U.S.C. §112, first paragraph.

The rejection is traversed for the following reasons.

The Examiner maintained that deposits are required.

However, Applicants have refuted that position to the extent that all of the starting materials for practicing the instant invention are readily available to the artisan. For example,

numerous strains of Phaffia, both wild-type and astaxanthin-overproducing strains, are available from depositories without restriction. All of the reagents for growing and treating the yeast are commercially available. Moreover, a method for obtaining a mutant Phaffia expressing high levels of astaxanthin is provided in the instant specification. In fact, a method which can be used to obtain a mutant Phaffia as claimed in the instant application is patented, see U.S. Patent No. 5,182,208.

The law is clear that a deposit is not required if the specification teaches a reproducible method for practicing a claimed invention and if the starting materials are readily available. That situation clearly applies as to the instant specification.

Rule 132 Declarations are of record to demonstrate the enabling nature of the instant specification and the instant invention. That Declaration executed 4 November 1997 provides evidence which demonstrate that practicing the methods set forth in the instant specification, over 100 examples of mutant Phaffia containing high levels of astaxanthin were obtained.

Clearly the evidence is highly probative on the reproducibility of the teachings of the instant specification and demonstrate that an artisan on practicing, for example, the patented method of obtaining mutant Phaffia with enhanced astaxanthin content as set forth in the instant specification and using available starting materials, will without undue experimentation obtain Phaffia which overexpress astaxanthin within the scope of the claimed invention.

Accordingly, deposits are not required, the instant specification is enabling, the claims are enabled and the rejection should be removed.

In item 21 on page 6 of the Office Action, claims 25-34 were rejected under 35 U.S.C. §112, first paragraph for an alleged want of enablement.

The rejection is traversed for the following reasons.

The instant invention can be practiced by use of, for example, a patented method for obtaining Phaffia with enhanced astaxanthin content. Therefore, the instant specification teaches a reproducible method for obtaining Phaffia within the scope of the claimed invention. There can be no doubt that the instant specification is enabled by clearly teaching how to make a Phaffia of interest using materials available to the artisan.

The instant specification provides numerous actual examples of Phaffia which fall within the scope of the instant claims. Thus, the application as filed clearly demonstrates that Phaffia with graded levels of astaxanthin above that found in wild-type Phaffia can be obtained by the practice of the instant invention. It is not seen how the instant specification which has resulted in two patents can be said to be non-enabling for multiple strains of yeast.

Moreover, as referred to hereinabove, Declarations of record demonstrate that by practicing the methods set forth in the instant specification, over 100 other examples of Phaffia with enhanced astaxanthin content which fall within in the scope of the instant claims were made.

It is unclear how such persuasive evidence cannot be considered to show that the instant specification teaches how to make a claimed Phaffia.

The Examiner also relied on the Fisher case. However, an examination of the facts revealed that in the Fisher case only one species of a claimed genus was disclosed.

On the other hand, the instant application and the Declaration evidence of record demonstrate numerous examples of Phaffia which fall within the scope of the instant claims. Therefore, the instant application, unlike the facts of the Fisher case, provides numerous examples which fall within the scope of the claimed invention . The instant invention is fully supported.

The Examiner relied on the Fiers case which relates to DNA.

The instant application relates to a specific type of yeast, Phaffia, identified by accepted and distinguishing binomial nomenclature and a specific recognizable mutant of that Phaffia. A taxonomic name provides clear and distinctive identification of the yeast of interest. There is one character of Phaffia of interest, overproduction of astaxanthin, which is more than adequately defined in the instant specification.

Attached hereto is a copy from a recent ATCC catalog demonstrating that there is but one species in the Phaffia genus. Moreover, Applicants are claiming only one specific characteristic arising from mutation and selection of such Phaffia and that is those Phaffia which have an enhanced content of astaxanthin.

Therefore, the Phaffia of interest are clearly identified by the taxonomic description of, and inherently all of the characteristics which exist in a Phaffia, and the Phaffia of interest have a character of interest, that is, the ability to overproduce astaxanthin.

The Examiner also equated a Phaffia with a DNA and believed that because description of a DNA requires knowledge of the base sequence, a Phaffia requires a precise definition such as by structure, formula, chemical name or other physical properties.

The Phaffia of interest is identifiable very readily by the unique binomial taxonomic nomenclature assigned therto. Type strains and all of the characteristics inherent thereto, are available. All that is needed to identify a microorganism is a name.

Moreover, the claimed Phaffia have a readily definable characteristic, namely enhanced astaxanthin content, which can be assessed visually or using other known methods.

The Examiner has not provided any explanation as to why the representations of enablement in the instant specification and in the record are unbelievable. Moreover, the Examiner has not provided any evidence in support of his position. Applicants believe there is no basis, on considering the record as a whole, to conclude there is a lack of enablement. MPEP 2164.04 and MPEP 2164.05.

The Examiner also relied on the Wands case with respect to enablement.

However, the Wands case is clearly in support of the enablement of the instant application. For example, Wands is related to the making of monoclonal antibodies which requires a fusion of two cell types, a culturing and growth of the hybrids of that fusion process and then a very detailed screening of the surviving hybrids to determine which produce monoclonal antibody and to determine which of those cells which produce monoclonal antibody, produce a monoclonal antibody of interest. The Federal Circuit found that while the entire process for making a monoclonal antibody can be long and tedious, it is a routine method and does not entail undue experimentation.

One of the methods for making mutant Phaffia of interest is to expose Phaffia to a mutagen and a selection agent and then to select those Phaffia which have enhanced astaxanthin content. That screening process can be mere visualization of cultures.

The mere visualization of cultures is much simpler than the screening process involved in the making of hybridomas which requires generally an RIA or ELISA for determining which cells secrete monoclonal antibody and then a similar if not same type of test to determine the specificity of those monoclonal antibodies. The method is clearly taught in the instant specification and no undue experimentation is required to practice the instant invention.

The actual experimentation required to obtain a Phaffia of interest is less involved than that set forth in Wands. Therefore, if Wands was found enabling for making hybridomas then clearly the instant method which technically is simpler than that of making monoclonal antibodies must be considered enabling as well.

Clearly, no undue experimentation is required to practice the instant invention. That is demonstrated by the actual examples of Phaffia falling within the scope of the instant claims provided in the specification as filed, as well as the numerous other examples of Phaffia which fall within the scope of the instant claims which were made practicing the instant specification as provided in the Declaration of record. Moreover, an artisan on reading that instant specification would know how to make and how to use the claimed invention.

Accordingly, a prima facie case of non-enablement has not been made, the instant specification is enabling, the claims are enabled and the rejection must be removed.

On page 8 of the Office Action, the claims were rejected under 35 U.S.C. §112, first paragraph allegedly because the instant invention was not described in the specification to demonstrate that the inventors were in possession of the claimed invention at the time the application was filed.

The rejection alleging want of written description is traversed for the following reasons.

Applicants fully believe that the instant specification clearly allows persons of ordinary skill in the art to recognize that the named inventors were in possession of the claimed invention at the time the first filed parental application, U.S. Serial No. 229,536 (hereinafter, "the '536 application"), was filed. The instant specification clearly conveys with reasonable clarity and particularity to those skilled in the art that the invention as claimed, namely, Phaffia with enhanced astaxanthin content, were in fact described in the instant specification in compliance with the Statute.

The instant specification provides a clear and reproducible teaching of how to make a claimed Phaffia with enhanced astaxanthin content and provides numerous actual examples of such Phaffia which fall within the scope of the claimed invention. All of the claim limitations are provided in the instant specification. The yeast is defined by the taxonomic designation thereof and the distinctive characteristic of interest, enhanced astaxanthin content. The subject matter of interest is defined clearly and distinctly.

Thus, the instant specification provides sufficient written description that the claimed invention was in the possession of the inventors at the time the '536 application was filed and moreover, on reading the record of the instant application, by way of the Rule 132 Declarations of record, clearly an artisan would well recognize that the claimed invention was in the possession of the named inventors at the time the '536 application was filed. Numerous strains which fall within the scope of the claims are provided in the instant specification. Clearly Applicants have provided the Examiner of a representative number of independently obtained and strains which support the claims.

Once again, the Examiner referred to the Fiers case which relates to chemical compounds and not to microorganisms, such as Phaffia.

Nevertheless, the instant application provides a taxonomic definition of Phaffia of interest and that definition provides a clear definition, explicitly and inherently, based on all of the inherent characteristics of a strain which comport with that taxonomic description, of the subject matter of interest.

Moreover, the instant specification provides a plurality of examples of a Phaffia which have enhanced astaxanthin content. That clearly defines the subject matter of interest and an artisan would be able to see, knowing that the starting material are available in the art, that the invention was practiced to a full extent. Numerous examples of Phaffia which fall within the scope of the claims are provided in the instant specification and thus clearly the inventors were in full possession of the claimed invention at the time the '536 application was filed.

It is believed the Examiner has not provided any evidence why an artisan would not recognize the instant specification describes the invention as claimed, namely, Phaffia overproducing astaxanthin. MPEP 2163.04. All of the claim limitations are described explicitly in the instant specification.

Therefore, clearly a legally sufficient written description is provided in the instant specification, the requirements of the Patent Statue have been complied with and the rejection can be removed.

In item 4 on page 12 of the Office Action, the claims were rejected under 35 U.S.C. §102(e) over U.S. Patent No. 5,712,110.

Attached hereto is a Rule 131 Declaration rendering the Fleno et al. patent an ineffective reference as to the instant application. The rejection can be removed.

CONCLUSION

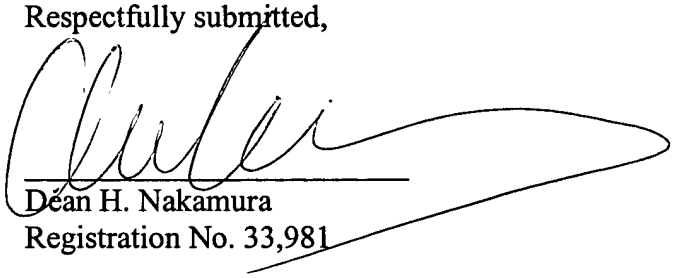
Applicants have endured extended prosecution in the instant application and firmly believe on the basis of having patents issue in previous filed applications in the patent family that the claimed invention is in full compliance with the Patent Statue and clearly is patentable.

Therefore, reexamination, reconsideration in view of the arguments herein and the record as a whole, withdrawal of the rejections and early indication of allowance are solicited earnestly.

If any issues remain outstanding, the Examiner is urged to contact the undersigned at the local exchange indicated hereinbelow so that a hasty resolution and allowance can be obtained without further delay.

Applicants hereby petition for any extension of time which may be required to maintain the pendency of the instant application and any required fee, except for the Issue Fee, for such extension is to be charged to Deposit Account No. 19-4880.

Respectfully submitted,



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60396 T.W. Jeffries NO_3-U-2. [NRRL Y-12889] Mutant derived from ATCC 32691. Enhanced fermentation of xylose to ethanol and growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60397 T.W. Jeffries NO_3-U-4. [NRRL Y-12890] Mutant derived from ATCC 32691. Enhanced fermentation of xylose to ethanol and growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60398 T.W. Jeffries NO_3-U-7. [NRRL Y-12891] Mutant derived from ATCC 32691. Enhanced fermentation of xylose to ethanol and growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60399 T.W. Jeffries U-NO_3-1. [NRRL Y-12892] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60400 T.W. Jeffries U-NO_3-5. [NRRL Y-12893] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60401 T.W. Jeffries U-NO_3-6. [NRRL Y-12894] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60402 T.W. Jeffries U-U-10. [NRRL Y-12895] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60403 T.W. Jeffries U-U-27. [NRRL Y-12896] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60404 T.W. Jeffries U-U-34. [NRRL Y-12897] Mutant derived from ATCC 32691. Rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

60405 T.W. Jeffries U-U-1. [NRRL Y-12898] Mutant derived from ATCC 32691. Nitrate negative, rapid growth on xylitol (Enzyme Microb. Technol. *6:* 254-258, 1984). (Medium 200 24C) **Shipped:** Freeze-dried.

64886 NRRL Y-2461. [IRIC 146] Extract of *Acacia mollissima,* West Germany. Conversion of D-xylose to ethanol (Adv. Biochem. Eng. Biotechnol. *27:* 73-83, 1983). (Medium 200 24C) **Shipped:** Freeze-dried.

64887 NRRL Y-2462. [IRIC 152] Extract of *Acacia mollissima,* West Germany. Conversion of D-xylose to ethanol (Adv. Biochem. Eng. Biotechnol. *27:* 73-83, 1983). (Medium 200 24C) **Shipped:** Freeze-dried.

64888 NRRL Y-2463. [IRIC 153] Shoe leather, France. Conversion of D-xylose to ethanol (Adv. Biochem. Eng. Biotechnol. *27:* 73-83, 1983). (Medium 200 24C) **Shipped:** Freeze-dried.

64889 NRRL Y-6704. [CBS 4045; IRIC 164] Extract of *Acacia mollissima,* West Germany. Conversion of D-xylose to ethanol (Adv. Biochem. Eng. Biotechnol. *27:* 73-83, 1983). (Medium 200 24C) **Shipped:** Freeze-dried.

Pachytichospora transvaalensis (van der Walt) van der Walt

52906 CBS 2186 ← J.P. van der Walt. Soil, South Africa. **Type culture** (The yeasts, a taxonomic study. 3rd ed. Kreger-van Rij, N.J.W., ed. Amsterdam: Elsevier Science Publishers; 1984:pp. 292-294; Bothalia *12:* 563, 1978). (Medium 200 24C) **Shipped:** Freeze-dried.

Paratorulopsis banhegyi Galgoczy *et* Novak: See *Torulaspora hansenii*

Phaffia rhodozyma Miller *et al.*

24201 H.J. Phaff 67-203. Fermenting red yeast. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

24202 H.J. Phaff 67-210. [CBS 5905; NCYC 874] Fermenting red yeast from *Fagus crenata,* Japan. **Type culture** (The yeasts, a taxonomic study. 3rd ed. Kreger-van Rij, N.J.W., ed. Amsterdam: Elsevier Science Publishers; 1984:pp. 890-892; Int. J. Syst. Bacteriol. *26:* 286-291, 1976). (Medium 200 24C) **Shipped:** Freeze-dried.

24203 H.J. Phaff 67-383. [CBS 5908] Fermenting red yeast. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

24228 H.J. Phaff 68-653C. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

24229 H.J. Phaff 67-202. Fermenting red yeast. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

24230 H.J. Phaff 67-385. Fermenting red yeast. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

24261 H.J. Phaff 67-484. Fermenting red yeast. Int. J. Syst. Bacteriol. *26:* 286-291, 1976. (Medium 200 24C) **Shipped:** Freeze-dried.

66270 E.A. Johnson ant -1 ← G.-H. An. Mutant derived from ATCC 24230. Production of astaxanthin (Appl. Environ. Microbiol. *55:* 116-124, 1989). (Medium 200 24C) **Shipped:** Freeze-dried.

66272 E.A. Johnson ant -1-4 ← G.-H. An. Mutant derived from ATCC 66270. Production of astaxanthin (Appl. Environ. Microbiol. *55:* 116-124, 1989). (Medium 200 24C) **Shipped:** Freeze-dried.

Pichia abadieae Jacob

22263 F. Jacob LY 1426. [CBS 6067; IFO 1822; NRRL Y-7499] Vegetable tanning liquors, France. **Type culture** (Bull. Soc. Mycol. Fr. *85:* 117-127, 1969). (Medium 200 24C) **Shipped:** Freeze-dried.

Pichia acaciae van der Walt: See *Yamadazyma acaciae*

Pichia adzetii Jacob

22262 F.H. Jacob LY 1425. [NRRL Y-7500] Vegetable tanning liquors, France. **Type culture** (Bull. Soc. Mycol. Fr. *85:* 117-127, 1969). (Medium 200 24C) **Shipped:** Freeze-dried.

Pichia ambrosiae van der Walt *et* Scott: See *Hormoascus ambrosiae*

Pichia amethionina* var. *amethionina Starmer *et al.*

36080 M. Miranda 76-401B. [CBS 6940] *Rathbunia alamosensis,* Mexico. **Type culture** (Int. J. Syst. Bacteriol. *28:* 435, 1978). (Medium 200 26C) **Shipped:** Freeze-dried.

Pichia amethionina* var. *pachycereana Starmer *et al.*

36079 M. Miranda 76-384A. [CBS 6943] *Pachycereus pringlei,* Baja California Sur Mexico. **Type culture** (Int. J. Syst. Bacteriol. *28:* 437, 1978). (Medium 200 26C) **Shipped:** Freeze-dried.

Pichia amylophila Kurtzman *et al.*

44361 NRRL YB-1287-82-3. [CBS 7022] Single-ascospore isolate of ATCC 44363. Characterization (Int. J. Syst. Bacteriol. *30:* 208-216, 1980). Mating type α. (Medium 200 24C) **Shipped:** Freeze-dried.

44362 NRRL YB-1287-82-2. [CBS 7021] Single-ascospore isolate of ATCC 44363. Characterization (Int. J. Syst. Bacteriol. *30:* 208-216, 1980). Mating type a. (Medium 200 24C) **Shipped:** Freeze-dried.

44363 NRRL YB-1287. [CBS 7020] Frass, loblolly pine, *Pinus taeda,* Mississippi. **Type culture** (Int. J. Syst. Bacteriol. *30:* 209, 1980). Diploid. (Medium 200 24C) **Shipped:** Freeze-dried.

Pichia angophorae Miller *et* Barker

22304 CBS 5823 ← M.W. Miller 65-106. [NRRL Y-7118; UCD 65-106] Exudate of red gum tree, *Angophora costata.* **Type culture** (The yeasts, a taxonomic study. 3rd ed. Kreger-van Rij, N.J.W., ed. Amsterdam: Elsevier Science Publishers; 1984:pp. 309-310; Antonie Leeuwenhoek J. Microbiol. Serol. *34:* 183-187, 1968). Pentose fermentation (Can. J. Microbiol. *28:* 360-363, 1982). (Medium 200 24C) **Shipped:** Freeze-dried.

Pichia angusta (Teunisson *et al.*) Kurtzman: See *Hansenula polymorpha*

Pichia anomala (Hansen) Kurtzman: See *Hansenula anomala*

Pichia antillensis Starmer *et al.*

56265 M. Miranda 82-604B h^+ ← H.J. Phaff. *Cephalocereus royenii,* Lesser Antilles. Characterization (Int. J. Syst. Bacteriol. *34:* 350-354, 1984). (Medium 200 25C) **Shipped:** Freeze-dried.

56266 M. Miranda 82-628B h^- ← H.J. Phaff. *Cephalocereus royenii,* Lesser Antilles. Characterization (Int. J. Syst. Bacteriol. *34:* 350-354, 1984). (Medium 200 25C) **Shipped:** Freeze-dried.

56267 M. Miranda 82-651A. [CBS 7111] *Cephalocereus royenii,* Lesser Antilles. **Type culture** (Int. J. Syst. Bacteriol. *34:* 350, 1984). (Medium 200 25C) **Shipped:** Freeze-dried.

Pichia barkeri Phaff *et al.*

64110 H.J. Phaff UCD-FST 83-1060.4. Rotting *Opuntia stricta* cladode, Caribbean Sea. Characterization (Int. J. Syst. Bacteriol. *37:* 386-390, 1987). (Medium 200 24C) **Shipped:** Freeze-dried.